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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MINNEAPOLIS, MN 55402-0903				
EXAMINER				
SUTTON, DARRYL C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,628

Applicant(s)

ANDERSEN, CARSTEN

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date 03/16/2007 & 07/12/2007

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "the ratio of resin to polyol is about 1:1 to about 10:1", and the claim

also recites "preferably from 2:1 to 8:1 and most preferably about 2.4:1" which are narrower statements of the range/limitation.

Claim 7 contains the trademark/trade name Amberlite^C IRP-64. Where a trademark or trade name (research designation) is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cation exchange resin and, accordingly, the identification/descriptions are indefinite.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the percent values recited by instant claims 2, 14-19 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., weight, volume, molar.

In order to overcome this ground of rejection the examiner recommends specifying the frame of reference used to determine the ratios.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walling (US 6,586,449) in view of Ferno et al., (US 3,845,217).

Walling teaches a nicotine product having a nicotine release rate of not less than 70% over a 10 minute period as well as a process to produce the product comprising steps (a) preparing an aqueous mixture of a polyol; (b) mixing said aqueous solution of the organic polyol with a cation exchange resin, (c) admixing with said mixture of step (b) an aqueous solution of nicotine to form a nicotine coated cation exchange resin admixture, and (d) removing water (Abstract). The preferred cationic exchange resin is Amberlite[®] IRP-64 (column 2, lines 41-46). Organic polyols include 1,3-dihydroxypropane, i.e. 1,3-propanediol, 1,4-hexanediol, glycerin, sorbitol, inositol, sucrose or glucose (column 2, lines 47-55 and column 3, lines 58-67). The ratio of cation exchange resin to polyol is from about 2:1 to about 4:1 and preferably about 2.5:1

(column 2, lines 59-63). The concentration of nicotine in an aqueous solution is from about 5% to about 40% by weight (column 2, lines 64-67). The most preferable ratio of cation exchange resin to nicotine is about 4:1 (column 3, lines 8-11). Polyols enhance the release rate of nicotine from the nicotine/resin mixture (column 4, lines 10-14).

Walling does not teach the specific order of method steps or a chewing gum.

Ferno et al. teaches chewing smoking substitute compositions (Abstract). A manufacturer of chewing gum can incorporate a solid complex of nicotine bound to a cation exchanger into gum compositions. The release rate of nicotine from the composition can be varied by varying the amount of nicotine which is bound to a given quantity of exchanger (column 3, lines 60-75 and column 4, lines 41-43). The cation exchanger must have cation exchanging groups in order to form a nicotine-ion exchange complex. The groups such as carboxylic, sulfonic and phosphonic groups are bound to a crosslinked polymer such as styrene and methacrylic acid (column 4, lines 20-57). Chewing gum compositions are formed by mixing the chewing gum mass with the nicotine-ion exchanger complex. The active ingredients are evenly and intimately distributed into the chewing gum (column 8, lines 5-20).

Ferno et al. does not teach the nicotine delivery product comprising a polyol.

The selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results, See MPEP2144.04, IV, C. Accordingly, it would have been obvious to modify the method steps to (a) first mix the aqueous nicotine solution with the cation exchange resin and to then mix the combination of nicotine and resin with the aqueous polyol solution. Further, since Ferno et al. teaches

that the release rate of nicotine can be varied by varying the amount of nicotine bound to the cation exchange resin, mixing the nicotine with the exchange resin in the first step would allow more nicotine to be bound to the resin before addition of the polyol, which is also taught to increase the delivery of nicotine.

In regard to claims 20 and 21, Walling does not teach the specific nicotine release rate. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Walling teaches a release rate of not less than 70% over a 10 minute period versus at least 80% over a 10 minute period of the instant claims.

In regard to claim 22, generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use the modified nicotine/ion exchange resin complex in the chewing gum of Ferno et al. as the nicotine source.

At the time of the invention, it would have been obvious to use the methods of Ferno et al. to insure that the nicotine ion exchange resin complex was evenly distributed in the chewing gum.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 6, 10-15 and 19-22 of copending Application No. 10/921199. The copending claims are drawn to a method of preparing a nicotine delivery product comprising mixing nicotine, a cation exchange resin, an organic polyol and water to form a mixture and removing the water; specific cation exchange resins and polyols; specific ratios between the components; and chewing gum compositions comprised of the delivery system.

The copending application differs from the instant application insofar as it discloses percentages of water in the composition. However, since the instant claims are drawn to aqueous solutions of nicotine and aqueous solutions of organic polyols and the last step of both methods is the removal of water, it can reasonably be assumed that solutions of the instant claims would be comprised of water in amounts that are

sufficient for the reactions between nicotine, exchange resin and polyol to take place. It would reasonably be expected that substantially the same delivery systems would be prepared by the methods of the instant application and the copending application since the instant claims are drawn to aqueous mixtures of both nicotine and polyol.

This is a provisional obviousness-type double patenting rejection.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is

(571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612